REMARKS

The Office Action mailed August 29, 2005, has been received and reviewed. Claims 1, 3-7, 10, 11, 16, and 21-25 are pending. Claim 9 is cancelled herein. Claims 2, 8, 12-15, and 17-20 were previously cancelled. Claims 1, 3-7, 9-11, 16 and 21-24 stand rejected. New claim 25 is presented herein. The application is to be amended as previously set forth. All amendments and cancellations are made without prejudice or disclaimer. No new matter has been added. Reconsideration is respectfully requested.

Support for new claim 25 can be found in at least paragraphs 10 and 11.

Interview Summary

Applicants extend their thanks to Dr. Priebe for the interview of Thursday, September 22, 2005. Pursuant to MPEP § 713.04, applicants state the following: applicants' representatives generally discussed the rejections including the rejection under 35 U.S.C. § 102(f). The Examiner stated that he believed a statement from the Assignee as to the inventors of the conflicting subject matter would likely address the issue. Further discussion included the Obviousness-type Double Patenting (ODP) rejections over US Patents 6,340,595 and 6,413,776, assigned to Galapagos Genomics ("Galapagos"). Applicants' representatives indicated that they did not believe a terminal disclaimer was necessary over US Patents 6,340,595 and 6,413,776 because, for example, no time-based extension of the patent monopoly was possible since the present application had an earlier priority date than the Galapagos' patents, and, under GATT, the patent life could not extend beyond the patent life of the Galapagos' patents. Applicants' representatives also thought, but were unsure, that the potential for harassment by multiple assignees would not apply in this case because of the relationship between Crucell Holland B.V. (hereinafter referred to as "Crucell") and Galapagos. Applicants' representatives have checked, and found this situation not to be the case. Further discussion included whether a terminal disclaimer would be necessary over the pending applications. The Examiner stated that a terminal disclaimer would only be necessary where the co-pending application might be allowed and issued before the instant application was able to issue, if allowed. No agreement was reached.

Assignment Information

The Examiner noted that the assignment records may not be complete. Applicants have filed appropriate assignments and respectfully request reconsideration.

Information Disclosure Statement

Applicants extend their thanks to the Examiner for his statements regarding the patentability of the instantly claimed invention vis-à-vis the documents filed with an Information Disclosure Statement on August 5, 2005, with respect to a European opposition procedure concerning a European patent issued from the international application related to the instant application.

Oath

The declaration stands objected to as allegedly being defective for not identifying the foreign priority documents. Applicants are submitting a substitute declaration and respectfully request reconsideration.

Specification

The specification is objected to because of certain informalities. The specification has been corrected per the suggestions of the examiner. Reconsideration and withdrawal of the objections is respectfully requested.

35 USC §102(f) Rejections

Claims 1, 3-7, 9-11, 16, and 21-24 stand rejected under 35 U.S.C. §102(f) because allegedly the inventors named did not invent the subject matter claimed. Applicants traverse the rejection.

It was noted that commonly assigned US Patent 6,395,519 (hereinafter referred to as the '519 patent) shares not all inventors with the instant application. The '519 patent named the five present inventors and an additional inventor not named on the present application, Govert Schouten. Applicants respectfully request reconsideration in light of the fact that Applicants have

corrected inventorship in US Patent 6,395,519 to remove Govert Schouten as an inventor. The correction is a matter of public record in the Office's files.

It was further noted that US Patents 6,340,595 and 6,413,776 (assigned to Galapagos), US Patents 6,878,549 and 6,447,768 (assigned to the assignee hereof under its former name Introgene B.V. (hereinafter referred to as "Introgene")); and applications 10/036,949 and 11/083,590 (with no recorded assignments) are not currently commonly assigned with the present application, but share some, but not all inventors in common with the present application. Further, it was also noted that US Patents 6,447,768, 6,670,188, 6,855,544, and 6,869,794, and, US Patent applications 10/002,750, 10/432,105, 10/494,140, 10/497,832, 10/512,589, 10/644,256, and 11/039,767 are currently commonly assigned with the present application, but either share no inventors with the present application or share only inventor Bout with the present application. The Office appears to be contending that the inventorship of all of the unrelated patents should be the same. Applicants respectfully disagree.

The presently claimed subject-matter has a priority date of June, 1995 and was disclosed in the parent applications to which the present application is related and from which it claims priority. The subject-matter was invented by the currently named five inventors. (See, Declaration of Dr. Abraham Bout (hereinafter referred to as the "Bout Declaration"), ¶¶ 3, 4, and 24). The priority applications were first filed in June 1995, followed by a PCT-application in June 1996 (PCT/NL96/00244), from which the current application is derived (the present application 10/618,526 is a continuation of application 10/125,751, which is a continuation of application 09/506,548, now US Patent 6,602,706, which is a divisional application of application 09/334,765, now US Patent 6,238,893, which is a continuation of application 08/793,170, now US Patent 5,994,128, which is a national entry application of PCT/NL96/00244). The PCT-application names the present five inventors. The other patents and patent applications (hereinafter referred to collectively as the "Unrelated Patents and Applications") have distinct inventorships of their own.

To summarize, applicants have filed declarations to the inventorship in the present application correctly establishing the inventorship of the claims of this patent application. Further, Applicants are of the view, considering that declarations were filed in the Unrelated Patents and Applications that do not claim priority to or from PCT/NL96/00244, that the inventorships of the

inventorships of the Unrelated Patents and Applications are correct as well.

In further response to the rejection, applicants are submitting a declaration by inventor Abraham Bout, Ph.D. (See, Bout Declaration). The Bout Declaration illustrates a timeline of the continuing research and further claimed subject matter. As can be seen, the Unrelated Patents and Applications were developed over the years by different inventive entities. (See, Bout Declaration, ¶¶ 6-24).

In view of the foregoing and the lack of any evidence to the contrary, Applicants request withdrawal of the rejection.

Double Patenting

Claim 9 stands rejected as allegedly being directed to the same deposited cell of claim 1 in prior US Patent 6,033,908. Claim 9 has been canceled, thus mooting the rejection.

Non-statutory double patenting

Applicants extend their thanks to the Examiner for accepting the terminal disclaimers filed on February 28, 2005 and April 1, 2005 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Patents 5,994,128, 6,033,908, 6,265,212, 6,306,652, and 6,692,966, and of patents granted on U.S. applications 10/125,751 and 10/219,414, *i.e.*, June 14, 2016. The terminal disclaimers have been recorded.

With respect to the obviousness-type double patenting (ODP) rejections generally, It should be noted that this case is not one for which an ODP rejection should apply. The claims of the present application are filed in a Specification that was published prior to the filing date **of all the patents** over which the claims of the present application have been rejected under ODP. Accordingly, all of the patents over which the claims of the present application have been rejected considered the disclosure and teaching of the Specification. Likewise, any patent issuing from the present claims will expire prior to **all of the patents** over which the claims of the present application have been rejected under ODP. Accordingly, there is no possibility of a time wise extension, and, as the claims are independent and distinct, the doctrine should not apply.

i) Rejections over patents

Applicants will first address the rejections of the various claims over issued patents.

Claims 1, 3-7, 9-11, 16 and 22 stand rejected under the judicially created doctrine of ODP as being allegedly unpatentable over claims 43 and 44 of US Patent 6,340,595 (hereinafter referred to as the '595 patent); claim 3 of US Patent 6,395,519 (hereinafter referred to as the '519 patent); claims 7, 32 and 35 of US Patent 6,413,776 (hereinafter referred to as the '776 patent). Claims 1, 3-7, 9, 16, 21 and 24 stand rejected under the judicially created doctrine of ODP as being assertedly unpatentable over claim 11 of US Patent 6,447,768 (hereinafter referred to as the '768 patent). Claims 1, 3-7, 9-11, 16 and 21-24 stand rejected under the judicially created doctrine of ODP as being assertedly unpatentable over claims 1-5 of US Patent 6,670,188 (hereinafter referred to as the '188 patent). Claims 1, 3-7, 9, 16 and 21 stand rejected under the judicially created doctrine of ODP as being assertedly unpatentable over claims 1-13 of US Patent 6,869,794 (hereinafter referred to as the '794 patent); claims 2, 4, and 6 of US Patent 6,878,549 (hereinafter referred to as the '549 patent); claims 15, 19 and 26 of US Patent 6,855,544 (hereinafter referred to as the '544 patent). The Examiner admits that the conflicting claims are not identical, but contends they are not patentably distinct from each other. Terminal disclaimers are filed herewith for the '519 patent, the '768 patent, the '188 patent, the '794 patent, the '549 patent, and the '544 patent, and reconsideration of the objections based on those patents is therefore respectfully requested.

At the outset, Applicants would request reconsideration of the assertion by the Examiner that the '549 patent is not assigned to Crucell. The Examiner contends that the patent is assigned to Introgene. However, a name change wherein Introgene changed its name to Crucell was recorded at reel/frame 013828/0651 on March 11, 2003. Accordingly, the '549 patent is assigned to Crucell.

ii) Background of the case

To begin, Applicants would discuss a general background of the claimed subject matter and the corresponding cited prior art. The present application has as an earliest filing priority date of June 15, 1995, which is a priority document for the PCT filing of June 14, 1996 (PCT/NL96/00244) from which the present application directly depends. PCT/NL96/00244

application was published as WO 97/00326 (hereinafter referred to as the '326 PCT publication) on January 3, 1997. Accordingly, the disclosure and teachings of that application, and therefore the currently claimed subject-matter, including the PER.C6 cells, were published not later than January 3, 1997.

The patents over which the claims of the present application stand rejected for allegedly ODP all have a priority date after the priority date of the current application, and later than the publication date of the current invention. The '595 patent was filed on July 21, 1999 as a Continuation-in-part (CIP) of application number 09/907,239, filed June 12, 1998 (now abandoned) and the '776 patent was filed on June 12, 1998. In tabular format, the priority dates and expiration dates of the instant application and the non-terminally disclaimed patents are as follows:

United States Patent	**United States Filing Date**	**Earliest Possible Priority Date**	**Publication Date**	**Expiration Date**
Present application	July 11, 2003	June 15, 1995	January 3, 1997	June 14, 2016
the '595 patent	July 21, 1999	June 12, 1998	January 22, 2002	June 12, 2018
the '776 patent	June 12, 1998	June 12, 1998	July 2, 2002	June 12, 2018

The earliest priority date for the patents cited against various claims of the present application is June 12, 1998. Accordingly, each of the '595 patent and the '776 patent considered the disclosure and teachings of the present application.

Applicants assert, therefore, in light of the fact that the teachings and disclosure of the present application were considered prior to the issuance of the claims of the '595 patent and the '776 patent, the subject-matter claimed therein is patentably distinct from the disclosure and teachings disclosed in the present application, as published in the '326 PCT publication. Indeed, the front pages of each of the '595 patent and the '776 patent demonstrate that the disclosure and teachings of the present application in the form of the '326 PCT publication was considered by the Office before grant of these patents. Therefore, this is an implicit *a priori* acknowledgement by the Office that the claims of at least those cited patents are not obvious and patentably distinct over the subject-matter disclosed, and now claimed, in the present application.

iii) No 'time-wise' extension possible

Applicants respectfully assert that the ODP rejections should be reconsidered because the granting of the claims of the present application would not be an unjustified extension of the patent grant, the main justification for an ODP rejection. In fact, there is no possibility that the claims of the present application will expire, according to patent term, later than June 14, 2016, in light of the twenty-year term from the filing date of the present application. Moreover, a terminal disclaimer has been filed to disclaim any portion of the term extending beyond the expiration of the '128 patent, June 14, 2016.

In fact, enactment of GATT 1994 (General Agreement on Tariffs and Trade 1994) should have begun the process to end the requirement of the judicially created doctrine of obvious-type double patenting for continuing applications, at least. Now, for all patents filed after June 8 1995, the term of the patent is generally twenty years from the earliest US filing date. Accordingly, continuing applications, whether they are divisionals, pure continuations, continuations-in-part, or the like, are all generally subject to a twenty-year term from the original filing date. Therefore, little risk exists for a 'time-wise' extension of the patent term for any application filed after June 8, 1995. Here, the present application was filed after June 8, 1995. The requirement for a terminal disclaimer is an expensive redundancy and is no longer needed based on the policies for which it was created.

Nonetheless, the claims of the present application have been rejected under the judicially created doctrine of ODP. A double patenting of the obviousness type rejection is "analogous to a failure to meet the non-obviousness requirement of 35 U.S.C. § 103, except that the patent principally underlying the double patenting rejection is not considered prior art." ***See, In re Longi,*** 759 F.2d 887, 892, 225 USPQ at 648 (Fed. Cir. 1985). In the present case, this is an unwarranted rejection and goes completely against the public policy for which the doctrine stands. Here, the art cited against the claims of the present application is not prior art and, therefore, could not be a valid statutory rejection. The use of the ODP doctrine to back in the rejection cannot be a correct application of the doctrine.

iv) ODP Analysis, One-way and Two-way

There are two standard analyses recognized for ODP, the "one-way" and the "two-way." The inquiry for a "one-way" double patenting rejection is "whether the claimed invention in the application for the second patent would have been obvious from the subject matter of the claims in the first patent, in light of the prior art" of the first patent. ***Carman Industries Inc. v. Wahl,*** 724 F.2d at 940, 220 USPQ at 481, 487 (Fed. Cir.1983). The "two-way" test is not applied in every situation. The Courts have recognized that in certain cases, especially when earlier filed applications are issuing later in time than later filed applications, a second type, the "two-way," analysis is appropriate for use in the double patenting inquiry. ***See In re Berg***, 140 F.3d 1428, 1434, 46 USPQ2d at 1230, 1231 (Fed. Cir. 1998) (The two-way test applies in the more unusual cases).

The two-way test is appropriate in the unusual circumstance where, *inter alia,* the United States Patent and Trademark Office ("PTO") is "responsible for the delay in causing the second-filed application to issue prior to the first." ***In re Berg,*** 140 F.3d at 1437, 46 USPQ2d at 1233; ***see also In re Goodman,*** 11 F.3d 1046, 1053, 29 USPQ2d 2010, 2016 (Fed.Cir.1993); ***Eli Lilly v. Barr***, 251 F.3d 955, 969 58 U.S.P.Q.2d 1865, 1876 (Fed. Cir. 2001). Some courts have required that the Office be "solely" responsible for any delay. ***See Id.*** However, the case law illustrates that the term "solely" has been interpreted liberally in certain unusual cases. ***See Symbol Technologies Inc. v. Opticon***, 935 F.2d 1569, 1579-1581 19 USPQ2d 1241, 1248-50 (Fed. Cir. 1991).

In ***Symbol Technologies***, the Federal Circuit affirmed a district court judgment in which the patent at issue was not found to be invalid for ODP. ***See Id.*** The patents at issue there, US Patent 4,387,297 (hereinafter referred to as the '297 patent) and US Patent 4,593,186 (hereinafter referred to as the '186 patent), generally related to devices that employed lasers to read bar codes symbols, and methods for their use. The invention claimed in the '297 patent was a laser scanning head that operates without physical contact with the bar code. ***See Id.***

During prosecution of the application that matured into the '297 patent, a restriction requirement was issued restricting the filed claims into six groups. Before the '297 patent issued, a divisional application directed to the originally non-elected Group VI claims, was filed. These

claims were described in the restriction requirement issued by the Office as a "method" of scanning, sensing and decoding bar code symbols. The divisional application led to a continuation application of the divisional application, which eventually, but subsequent to the issuance of '297, issued as the '186 patent. The issue before the Court of Appeals for the Federal Circuit was whether the '186 patent was invalid for ODP because the continuation was filed on claims covering further embodiments from the claims of the original restriction requirement. ***See Id*** at 1572-73, 19 USPQ2d at 1244.

In its reasoning, the Court stated that the '186 patent contains apparatus claims 1 through 10 and method claims 11 through 15. The Court noted that the method claims closely corresponded to the Group VI claims of the original application. ***See Id.*** The '186 patent claimed a system that repetitively scans and senses a bar code symbol each time a user depresses the trigger. Opticon had alleged that the '186 patent was invalid for ODP over the '297 patent.

The court rejected Opticon's contention that there was no consonance between the claims in the '186 patent and the non-elected Group VI claims from the prosecution of the '297 patent. ***See Id.*** Therefore, the '186 patent was entitled to the benefits of 35 U.S.C. § 121, which removes the original patent as a reference under ODP as the '186 patent was a divisional application of the '297 patent.

Here, the claims of the '595 patent and the '776 patent would have been restricted from the claims of the present application if the claims had been filed together, as will be more clearly illustrated herein. Accordingly, the claims of the present application and of the '595 and the '776 patents would be afforded the protection of §121 if they had been filed in the same application (although, they could not have been as they were invented later). However, as has been fully explained previously, the '595 and the '776 patents were invented by different inventive entities on different dates and were regarded by the Office as independent and distinct inventions. However, and very instructive for the present claims, the Court of Appeals for the Federal Circuit, in the ***Symbol Technologies*** case, also considered what the result would have been if the principle of consonance was violated in the divisional application and the application was, therefore, not entitled to the benefit of section 121, *i.e.*, no protection from an ODP rejection. ***See Id*** at 1579-80, 19 USPQ2d at 1249. The Federal Circuit focused its analysis on whether the claims of the patents

claims of the patents were different.

According to the Court, the claims of the '297 and the '186 patents were different because the claims of the '186 patent recited additional features. ***See Id*** at 1581, 19 USPQ2d at 1250. The Court stated that the primary question in all ODP rejections is whether the claims are patentably distinct. ***See Id; see In re Borah,*** 354 F.2d 1009, 1017, 148 USPQ 213, 220 (CCPA 1966) (crux of ODP inquiry lies in comparison of claims); ***see also Gerber Garment Technology, Inc. v. Lectra Systems, Inc.,*** 916 F.2d 683, 685, 16 USPQ2d 1436, 1438 (Fed.Cir.1990)(judicially created doctrine of ODP applies when two applications or patents, not drawn to precisely the same invention, are [allegedly] "drawn to inventions so very much alike as to render one obvious in view of the other and to effectively extend the life of the patent that would have the earlier of the two issue dates"). Accordingly, the primary concern for the Office should be whether the claims of the cited patents and the claims of the present application are patentably distinct, *e.g.*, whether additional elements are recited.

Further, it appears quite clear from the outset that for an ODP rejection, not being a statutory rejection, but one under a judicially created doctrine, the particular facts of the case at issue need to be considered in a detailed and careful manner, in order to prevent an inappropriate application of the doctrine without giving sufficient weight to the reasons as to why the doctrine was established, and hence to prevent from reaching a inequitable conclusion.

The fundamental reason for the rule against double patenting is *to prevent unjustified time-wise extension of the right to exclude granted by a patent.* It is submitted that in the absence of this prerequisite, no ODP rejection is warranted. Should it however be argued that another reason for an ODP rejection would be the possibility of multiple suits against an infringer by multiple assignees of the same invention (as is believed by applicants not to be a justification when standing on its own, but for the sake of argument the following discussion is provided), applicants would respectfully submit at least the following, not necessarily extensive, reasons why an ODP rejection based on that criterion should not be made at least in the present situation:

a) it is a matter of economic reality that a single entity that practices multiple inventions at the same time runs the risk of being sued for the infringement of multiple patents, wherein each of the patents covers a separate invention. This risk is fully independent of whether the different

different aspects are patented by one or by more than one entities, *i.e.*, should one process or product be within the claim scope of two different and independent inventions that are owned by different third parties, there is a risk of being sued by both parties while infringing with the same process or product. No statutory law or judicially created doctrine would prevent this. In the current situation, the two unrelated patents happen to share one common inventor (without sharing all inventors). There is no reason why this should have any impact on the situation as described above: this fact seems a mere coincidence.

b) If the subject-matter of the unrelated '595 and '776 patents were invented by another inventive entity, no reason would exist to invoke an ODP rejection.

c) The common inventor, Dr. Bout, has no extant rights in the application at issue or in the unrelated '595 and '776 patents, since these all have been assigned to corporate assignees.

d) If ODP rejections as in the present situation were justified, this could have a severe impact on the industry in general: since it is not uncommon for inventors to be involved in making more than one separate invention, and since it is also common for inventors to switch from one employer to another, there appears to be a great risk that an inventor making a first invention at employer A (and applying for a patent therefore, assigning to employer A) and subsequently making an unrelated invention at employer B (and applying for a patent therefore, assigning to employer B), that if the inventor (or a co-inventor) would include knowledge which was invented earlier by him, but may now even be public, in the later application and especially in subclaims to for instance a preferred embodiment, that the later application may nevertheless be held against the earlier application in an ODP rejection, and that there would be no remedy for the first employer because the applications are not commonly assigned, and hence the first employer would not be able to obtain the desired patent, only because one of the inventors has moved to another employer and made an independent invention.

d) Also in view of the foregoing arguments, it seems clear that if an ODP rejection were justified based solely upon the possibility of harassment by multiple assignees (*i.e.*, in the absence of the possibility of a time-wise extension), that an ODP rejection could only be made upon a narrow interpretation of "the same invention", and hence that the inventions on which a patent is sought and the patents held against it should be really directed to the same invention that is not patentably distinct. *This leads to the conclusion that in such case an ODP rejection could* ***only*** *be*

only *be warranted when a* ***two-way analysis*** *would lead to the conclusion that the subject-matter is not patentably distinct.* Hence, in the present case, applicants should be entitled to a two-way analysis for the ODP issue relating to the unrelated '595 and '776 patents.

v) Court sanctioned right to file patent claims covering a competitor's product

Further, it has been recognized and approved by the Federal Circuit to file a patent application for the purpose of obtaining a right to exclude a competitor's product from the market. It is not in any manner improper to file an application, to amend, or to insert claims intended to cover a competitor's product the applicant has learned about during the prosecution of a patent application. ***See, Kingsdown Medical Consultants, Ltd. v. Hollister Inc.,*** 863 F.2d 867, 9 USPQ2d 1384 (Fed. Cir. 1988). Here, in the present case, this is precisely why the present application was filed, to cover a potential product of a competitor. Accordingly, the filing is sanctioned by the courts. Therefore, this is a situation where the "two-way" analysis should be used since the manner in which the claims arose has been specifically sanctioned by the courts.

vi) Public policy

One policy ground upon which an obviousness-type double patenting rejection is issued rests fundamentally on the doctrine that the public should be able to act on the assumption that upon the *expiration* of a patent it will be free to use not only the invention claimed in the patent, but also modifications or variants which would have been *obvious* to those of ordinary skill in the art at the time the invention was made, taking into account the skill of the art and prior art other than the invention claimed in the issued patent. ***See, In re Zickendraht,*** 319 F.2d 225, 232, 138 USPQ at 28 (C.C.P.A. 1963) (Rich, *J.,* concurring). Here, the term of any claim issuing is June 14, 2016. As well, the present application contains a terminal disclaimer over the '128 patent and therefore explicitly expires at the expiration of the '128 patent.

Further, in the present case, considering the filing dates of the '595 patent and the '776 patent, occurring after publication of the disclosure of a parent application to the present application, the Office should apply the "two-way" test for the obviousness-type double patenting rejection out of realization that this is an unusual case.

Strong policies exist to encourage an applicant to claim all that is disclosed in an

application. It is the law that what is disclosed in an application and not claimed is dedicated to the public. ***See Johnson & Johnston Associates Inc. v. R.E. Service Co., Inc.***, 285 F.3d 1046, 1055, 1056, 62 USPQ2d at 1230, 1231 (Fed Cir 2002). The Court explained that application of the doctrine of equivalents to recapture subject matter deliberately left unclaimed would conflict with the primacy of the claims in defining the scope of the patentee's exclusive right. ***See Id***; ***Sage Prods. Inc. v. Devon Indus., Inc.***, 126 F.3d 1420, 1424, 44 USPQ2d at 1106, 1107 (Fed.Cir.1997). Accordingly, any unclaimed subject matter in a specification would be dedicated to the public and available for the public's use. Therefore, patentees should claim all disclosed embodiments to prevent a dedication, ***See, e.g., Johnson & Johnston Associates Inc.***, 285 F.3d at 1055, 62 USPQ2d at 1230. In all fairness, the Examiner should apply the "two-way" test to determine patentability because Applicants are claiming only what is permitted.

Accordingly, the Examiner should apply the "two-way" test for patentability with regard to the cited '595 patent and the '776 patent (hereinafter collectively referred to as the "Unrelated Patents)".

Applicants further assert that at least the second prong of the "two-way" test has already been performed by the Office during the prosecution and examination of those patents, *i.e.*, are the claims in those patents patentably distinct and non-obvious in view of the specification of the present application, which was published prior to the priority dates of the cited patents? The grant of those patents by the Office indicates that the claims therein were considered novel and non-obvious over the disclosure of the present application and hence over the present claims, since the disclosure of the present invention has been considered by the Office during the examination that led to the granting of the cited patents. In fact, the PCT publication of the parent '128 patent is listed on the front page of all the cited patents. Indeed, as also indicated by the Examiner during the interview, it is clear from its face that the subject-matter of the claims of the cited '595 patent and the '776 patent relates to a different invention than the invention as currently claimed. Therefore, it is clear from the outset that when a two-way test is applied, the claims of the earlier granted '595 and '776 patents are not obvious and thus patently distinct from the present claims. This leads to the conclusion that once a two-way test was applied, no ODP rejection would be made over the '595 and '776 patents.

vii) *In re Braat* analysis

The reasoning of the ***In re Braat*** case also illustrates that the ODP rejections of at least the Unrelated Patents are not well made. *In re Braat*, 937 F.2d 589, 19 USPQ2d 1289 (Fed. Cir. 1991). The facts of the ***In re Braat*** case are that two inventors, Dil and Braat, both employed by the same corporation, both filed patent applications. The Braat application claimed priority from a parent application filed April 3, 1978 and a continuing application filed July 17, 1978. The Dil application was filed on January 31, 1979 and issued June 24, 1980. The Braat application and the Dil patent both were concerned with optical record carriers. In fact, the Court noted that the later filed, but earlier issued Dil patent claimed a combination incorporating the invention of the Braat application and particularly mentioned the Braat application in the specification. During prosecution, the Braat application was rejected over the Dil patent under the ODP doctrine.

In response, Braat argued that the two-way analysis should be applied in determining whether the ODP rejection was proper. The Office disagreed. Braat then appealed to the Board and the Board affirmed the rejection. Braat further appealed. The sole issue appealed was whether Braat was entitled to the two-way analysis under the ODP doctrine.

The Federal Circuit began by recognizing that characterizing the later filed, but earlier issuing Dil patent as an improvement of the earlier filed, but still pending, Braat application was problematic because the definition of an improvement necessarily implies that it was developed specifically for use with the basic invention. However, the court recognized that the Dil patent was totally separate from that of the Braat application. The court recognized that inventions may be independent, but, when jointly used, may complement one another. The Court stated that a better characterization of the relationship between the inventions is as combination/sub-combination. Both the Dil patent and the Braat application are independent inventions, but a combining of the two sub-combinations provides for a third invention, the combination, as is a claimed embodiment in the Dil patent.

Further, because of the different inventive entities and different filing dates, Braat could not have filed his earlier filed invention in the Dil application. The court determined that it was not Braat's fault that the claims of the Dil patent issued first.

The court found another reason to allow the claims of the Braat application over the claims

claims of the Dil patent because the claims of the Braat application were patentably distinct from the claims of the Dil patent.

In comparison to the claims of the present application: (1) The priority date, June 15, 1995, is well before the priority date of the '595 patent and the '776 patent, June 12, 1998. (2) The claims of the Unrelated Patents have already issued. (3) The claims of the Unrelated Patents issued over the disclosure of the present application. (4) The Unrelated Patents both particularly disclose a parent to the present application. (5) The inventive entities of the Unrelated Patents are different. (6) And, most importantly, the claims of the present application are patentably distinct from the claims of the Unrelated Patents. Accordingly, in light of the overwhelming similarities of the ***In re Braat*** case and the present application, the Examiner should follow the reasoning of the court and apply the 'two-way' analysis.

ix) Response

Now, Applicants respond specifically to each of the remaining ODP rejections: First, the primary reason an ODP rejection was created was to prevent the 'time-wise extension' of a patent grant. Here, in each instance, the 'time-wise' extension is not a concern. Each of the patents over which the claims of the present application are rejected, will expire later in time than any of the present claims. The claims of the present application would expire on June 14, 2016. Accordingly, the primary policy reason for an ODP rejection does not exist. Likewise, the primary analysis conducted for an ODP rejection, whether the claims are patentably distinct, illustrates that the ODP rejections should be removed because the claims of the '595 patent and the '776 patent are patentably distinct from the present claims, as they recite additional features. ***See Symbol Technologies Inc***, 935 F.2d at 1579-1581 19 USPQ2d at 1248-50***; see In re Borah,*** 354 F.2d at 1017, 148 USPQ at 220; ***see also, Gerber Garment Technology, Inc.***, 916 F.2d at 685, 16 USPQ2d at 1438. Here, the restriction requirement made in the priority filing, a parent application, clearly illustrates the independent and distinctness of the claims of the present invention, as illustrated below.

The restriction requirement in a parent application, USSN 08/793,170 (hereinafter referred to as the '170 application), to the present application was for two groups. Group I was directed to

directed to expression vectors and packaging cell lines, classified in Class 435[1], subclass 172.3[2], 320.1[3], and 325[4]. Group II was directed to a method for intracellular amplification comprising the step of providing a cell with a linear DNA fragment to be amplified, classified in Class 435, subclass 6[5].

a) Galapagos Patents

As to the asserted rejection of claims 1, 3-7, 9-11, 16, and 22 under ODP as allegedly unpatentable over claims 43 and 44 of the '595 patent, Applicants respectfully traverse in light of the claims and the following analysis and respectfully request reconsideration.

As a first matter, Applicants would point out that the claims of the '595 patent could not have been filed with the claims of the present application as the claims of the '595 patent were not invented until later. (See the Bout Declaration, ¶ 8).

Furthermore, even if such claims would have been invented earlier and presented in the same (phantom) application, they would have been restricted out of the phantom application.

Applicants present independent claim 1 of the '595 patent immediately following:

> 1. A library of a multitude of unique expressible nucleic acids, said library including:
> a multiplicity of compartments, each of said compartments consisting essentially of one or more adenoviral vector comprising at least one unique nucleic acid of said library in an aqueous medium,
> wherein said adenoviral vector is capable of introducing said nucleic acid into a host cell, is capable of expressing the product of said nucleic acid in said host cell, and is deleted in a portion of the adenoviral genome necessary for replication thereof in said host cell.

As can be seen, claim 1 of the '595 patent is directed towards 'a library of a multitude of unique expressible nucleic acids.' Such claim language does not fit well within either group of the original restriction requirement of the '170 application made in a parent to the present application because the claims of the '595 patent are patentably distinct from the claims of the present

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[1] Class 435: Chemistry

[2] Subclass 172.3:Mutation or Genetic Engineering (Recombination)

[3] Subclass 320.1:Vector, Per Se (E.G., Plasmid, Hybrid Plasmid, Cosmid, Viral Vector, Bacteriophage Vector, Etc.) Bacteriophage Vector, Etc.

[4] Subclass 325:Animal Cell, Per Se (E.G., Cell Lines, Etc.); Composition Thereof; Process of Propagating, Maintaining or Preserving An Animal Cell or Composition Thereof; Process of Isolating or Separating An Animal Cell or Composition Thereof; Process of Preparing a Composition

present application. ***See Symbol Technologies Inc***, 935 F.2d at 1579-1581 19 USPQ2d at 1248-50. Clearly, the claims of the '595 patent recite additional elements. The subclasses assigned to the claims of the '595 patent were 457[5], 235[6], and 325. The claims of the present application and the claims of the '595 patent both share subclass 325. However, the differences in the other subclasses are significant. Accordingly, the Office considered the claimed invention of the '595 patent to be patentably distinct from the claimed disclosure of a parent to the present application. Therefore, the claims of the present application and the claims of the '595 patent should be afforded the protections against an ODP rejection pursuant to Section 121. ***See Id.*** No question exists that the claims of the '595 patent would have been restricted from the claims of the present application and as Applicants have already terminally disclaimed to the '128 patent, no question exists that the Office considered the claims of the present application to not be patentably distinct from the claims issuing from the '128 patent. Therefore, the claims of the present application should be afforded the protection against an ODP rejection pursuant to Section 121.

Nonetheless, provided the Office is determined to maintain the ODP rejections, a two-way analysis should apply. In general, when a later filed patent issues first, a two-way analysis should apply, provided the later issuance is not due to the applicant. ***See, Eli Lilly v. Barr***, 251 F.3d at 969

The "two-way" test requires the resolution of two issues. First, as before, an obviousness determination of the claims of the present application must be made in light of the claims of the first issued patent. Here, Applicants assert that the claims of the present application and the claims of the '595 patent would have been restricted, as illustrated above, and are therefore not amenable to the first part of the analysis, as the claims are drawn to independent and distinct inventions. As for the second part of the analysis, the claims of the first issued patent must be determined to be merely obvious over the claims of the claims of the present application. ***See, Carman Industries,*** 724 F.2d at 940, 220 USPQ at 487. Here, the claims of the first issued patent are not merely obvious over the claims of the present application. Indeed, this was acknowledged by the Examiner during the interview wherein he indicated that it is clear from its face that the

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Composition Containing An Animal Cell; Culture Media Therefore

[5] Subclass 457: Process Of Mutation, Cell Fusion, or Genetic Modification With Helper Virus Present

[6] Subclass 235: Virus or Bacteriophage, Except For Viral Vector or Bacteriophage Vector; Composition Thereof; Preparation Or Purification

face that the earlier granted patent relates to a different invention than the currently claimed invention. Therefore, should a two-way test be applied, it is clear that the present claims are not to be rejected under the ODP doctrine over claims of the '595 patent.

An obviousness analysis requires consideration of the ***Graham*** factors: (1) scope and content of the prior art; (2) differences between the prior art and the claimed invention; and, (3) the level of ordinary skill in the art. ***See, Graham v. John Deere Co.***, 383 U.S. 1, 17, 86 S.Ct. 684, 15 L.Ed.2d 545 (1966). (Obviousness is a question of law based on findings of underlying facts relating to the prior art, the skill of the artisan, and objective considerations.). Under an ODP analysis, the indicia of non-obviousness are not considered. Stated in another manner, in reviewing an ODP rejection, one construes the claim in the earlier patent with the claim in the later patent or application and determines the differences. Second, the court determines whether the differences in subject matter between the two claims render them patentably distinct.

As stated, applicants will compare issued claim 43 of the '595 patent in light of present claim 1 to determine if it is obvious. The scope and content of claim 1, in light of the prior art to claim 1, are presented below. Claim 1 (of the instant application) is presented in various elements, without prejudice or disclaimer, to more easily establish the similarities and differences between present claim 1 and claim 43 (of the '595 patent): (1) An isolated adenovirus packaging cell comprising in its genome (2) a first nucleic acid sequence encoding (2a) adenovirus E1A and E1B gene products, but (2b) lacking a nucleic acid sequence encoding adenovirus pIX.

Claim 43 of the '595 patent is dependent from claim 15 therein, and therefore should read as follows:

> A process for producing a library consisting of a multitude of unique expressible nucleic acids arranged in a multiplicity of compartments, each said compartment consisting essentially of replication deficient adenoviral vector comprising at least one of said unique nucleic acids, comprising:
> transfecting (a) a PER.C6 cell or a cell derived from a PER.C6 cell harboring a first portion of the adenoviral genome integrated into its genome, with an admixture of (b) a nucleic acid delivery vehicle containing said unique nucleic acid operably linked to a promoter and further containing a second portion of the adenoviral genome, said second portion comprising at least one adenoviral ITR, and (c) a helper nucleic acid consisting essentially of a third portion of the adenoviral

adenoviral genome;
wherein the sequence of said first portion of the adenoviral genome does not overlap with the sequences of either the second or third portions of adenoviral genome, and
wherein the first, second and third portions of adenoviral genome are arranged such that all adenoviral proteins essential for replication and encapsidation are capable of expression in said packaging cells.

The underlined portion herein indicates at least some of the differences between the claim 43 of the '595 patent and present claim 1. As can be seen, claim 43 of the '595 patent relates to a process for producing a library that can be used in functional genomics. Present claim 1 relates to a cell. The underlined portion of claim 43 indicates additional elements that are not present in claim 1. For example, and not by way of limitation, claim 43 contains at least the additional elements of:

1) a process for producing a library consisting of a multitude of unique expressible nucleic acids arranged in a multiplicity of compartments;

2) that the nucleic acid is operably linked to a promoter;

3) a second portion of the adenoviral genome, said second portion comprising at least one adenoviral ITR;

4) a helper nucleic acid consisting essentially of a third portion of the adenoviral genome; and

5) various restrictions on the assemblies of the above stated additions.

Claim 1 does not disclose any of these elements and relates to completely different patentable subject matter. Likewise, claims 3-7, 10, 11, 16, and 21-25 do not disclose these elements. A proper ODP rejection analysis is limited to the disclosed claims. ***In re Bartfeld***, 925 F.2d 1450, 17 USPQ2d 1885 (Fed. Cir. 1991). Accordingly, considerable non-obvious differences exist between claim 43 of the '595 patent and present claim 1.

The level of ordinary skill in the art would be high at a Ph.D. with relevant work experience. Applicants arrive at this "ordinary person" from at least the fact that the inventors hereof have a Ph.D. with more than five years of experience. Accordingly, one of ordinary skill in the art would have the education to understand the molecular biology associated with an adenovirus and two years of practical working experience.

In conclusion, the differences between claim 1 and claim 43 and the skill in the art clearly indicate that claim 43 is not obvious when compared to present claim 1 or any of the claims dependent thereon.

The same reasoning applies mutatis mutandis for claim 44 of the '595 patent, which is dependent from claim 43 therein, and therefore claim 44 of the '595 patent is not obvious when compared to present claim 1 or any of the claims dependent thereon, for at least the same reasons as indicated for claim 43 of the '595 patent.

A further reason exists as to why the claim 1 is valid under ODP as compared to claims 43 and 44 of the '595 patent is that since the presently claimed subject-matter was publicly disclosed by the time the earliest priority document of the '595 patent was filed (June 12, 1998), the granted '595 claims fulfilled the criteria for patentability, *i.e.*, are novel and non-obvious over the present claims and underlying disclosure. Therefore, the allegation that the claims are not patentably distinct is unjustified. Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1, 3-7, 9-11, 16, and 22 in light of this response and the amendments.

Claims 1, 3-7, 9-11, 16, and 22 stand rejected under ODP as allegedly unpatentable over claims 7, 32, and 35 of the '776 patent, Applicants respectfully request reconsideration in light of an analysis of the claims and the following analysis.

As previously stated, a primary purpose of the judicially created doctrine of ODP rejection is to prevent the 'time-wise extension' of the patent grant. Here, that is not a concern. The issuance of the present claims would not give rise to an unjustified or improper time-wise extension of the right to exclude granted by a patent. The '776 patent, over which the claims of the present application are rejected, will expire later in time, on June 12, 2018. The claims of the present application will expire no later than June 14, 2016. Accordingly, the underlying policy reasons for a double patenting rejection do not exist.

Applicants also point out that the claims of the '776 patent could not have been filed with the claims of the present application as the claims of the '776 patent were not yet invented and would have been restricted even if they had been invented. See, Bout Declaration, ¶ 8.

Applicants present independent claim 1 of the '776 patent immediately following:

1. A method of producing a recombinant adenoviral vector library consisting of

distinct recombinant adenoviral vectors, wherein each distinct vector contains an unique nucleic acid, by:
growing a plurality of cell cultures, each said cell culture containing at least one cell comprising adenoviral nucleic acid sequences consisting essentially of adenoviral E1-complementing sequences, and
transfecting, into said at least one cell of each said cell culture, an adapter plasmid and a recombinant nucleic acid, under conditions such that said recombinant adenoviral vector library is produced, wherein
(A) i) said adapter plasmid comprises adenoviral nucleic acid sequence but does not comprise E1 region sequences that overlap with E1 region sequences in said at least one cell and E1 region sequences that overlap with E1 region sequences in said recombinant nucleic acid, wherein said overlap would otherwise result in generation of replication competent adenovirus in said at least one cell,
ii) said adapter plasmid further does not comprise E2B region sequences other than essential E2B sequences, E2A region sequences, E3 region sequences and E4 region sequences,
iii) said adapter plasmid further comprises, in operable configuration, a nucleic acid sequence coding for a functional Inverted Terminal Repeat, a functional encapsidation signal, and sufficient adenoviral sequences to allow for homologous recombination with said recombinant nucleic acid, and a promoter and a unique nucleic acid sequence operatively linked to said promoter; and wherein
(B) said recombinant nucleic acid comprises, in operable configuration, a sequence for a functional Inverted Terminal Repeat and adenoviral sequence sufficient for replication, wherein said recombinant nucleic acid sequence partially overlaps with sequence of said adapter plasmid to allow for homologous recombination resulting in replication-defective, recombinant adenoviral vector.

As can be seen, claim 1 of the '776 patent is directed towards "[a] method of producing a recombinant adenoviral vector library consisting of distinct recombinant adenoviral vectors." Such claim language does not fit well within either group of the original restriction requirement made in a parent to the present application because the claims of the '776 patent are patentably distinct from the claims of the present application. ***See Symbol Technologies Inc***, 935 F.2d at 1579-1581 19 USPQ2d at 1248-50. Clearly, the claims of the '776 patent recite additional elements. The subclasses assigned to the claims of the '776 patent were 462[7], 463[8], 325.1, and 325. The claims of the present application and the claims of the '776 patent both share subclass 325. However, the differences in the other subclasses are significant. Accordingly, the Office considered the claimed invention of the '776 patent to be patentably distinct from the claimed

[7] Process of Mutation, Cell Fusion, or Genetic Modification Involving Site Specific Recombination

disclosure of a parent to the present application. Therefore, the claims of the present application and the claims of the '776 patent should be afforded the protections against an ODP rejection pursuant to Section 121. ***See, Id.*** No question exists that the claims of the '776 patent would have been restricted from the claims of the present application and as Applicants have already terminally disclaimed to the parent patent of the '128 patent, no question exists that the Office considered the claims of the present application to not be patentably distinct from the claims issuing from the '128 patent. Therefore, the claims of the present application should be afforded the protections against an ODP rejection pursuant to Section 121. ***See, Id.***

Nonetheless, provided the Office is determined to maintain the ODP rejections, a two-way analysis should apply. In general, when a later filed patent issues first, a two-way analysis should apply, provided the later issuance is not due to the applicant. ***See, Eli Lilly v. Barr***, 251 F.3d at 969.

The "two-way" test requires the resolution of two issues. First, as before, an obviousness determination of the claims of the present application must be made in light of the claims of the first issued patent. Here, applicants assert that the claims of the present application and the claims of the '776 patent would have been restricted, as illustrated above, and are therefore not amenable to the first part of the analysis, as the claims are drawn to independent and distinct inventions. As for the second part of the analysis, the claims of the first issued patent must be determined to be merely obvious over the claims of the claims of the present application. ***See, Carman Industries***, 724 F.2d at 940, 220 USPQ at 487. Here, the claims of the first issued patent are not obvious over the claims of the present application.

Present claim 1 reads as previously indicated. Claim 7 of the '776 patent is dependent from claim 4 therein, and therefore should be read as follows:

> A method of producing a recombinant adenovirus vector library consisting essentially of a plurality of cell cultures containing distinct recombinant adenoviral vectors each containing a unique nucleic acid, by: growing a plurality of cell cultures, each said cell culture containing at least one cell, said at least one cell comprising adenoviral E1-complementing sequences; and

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[8] Process of Mutation, Cell Fusion, or Genetic Modification Involving General or Homologous Recombination

transfecting, under conditions whereby said recombinant adenovirus vector library is produced, said at least one cell with
i) a first recombinant nucleic acid comprising adenoviral sequence coding, in operable configuration, for one functional Inverted Terminal Repeat, and sequence coding for a promoter and a unique nucleic acid operatively linked to said promoter; and
ii) a second recombinant nucleic acid comprising adenoviral sequence coding, in operable configuration, for one functional Inverted Terminal Repeat and sufficient for replication, wherein said second recombinant nucleic acid does not comprise the adenoviral E1 region,
wherein one of said first or second recombinant nucleic acids comprises a functional encapsidation signal,
wherein at least one of said plurality of cell cultures is a PER.C6 cell culture.

The underlined portion herein indicates at least some of the differences from present claim 1. As can be seen, claim 7 of the '776 patent relates to a method of producing a recombinant adenovirus vector library that can be used in functional genomics, whereas present claim 1 relates to an isolated adenovirus packaging cell comprising in its genome a first nucleic acid molecule encoding adenovirus E1A and E1B gene products but lacking a nucleic acid sequence encoding adenovirus pIX. For example, and not by way of limitation, claim 7 contains at least the following six additional elements of:

1) A method of producing a recombinant adenovirus vector library;
2) a plurality of cell cultures containing distinct recombinant adenoviral vectors each containing a unique nucleic acid, by:

growing a plurality of cell cultures, each said cell culture containing at least one cell, said at least one cell comprising adenoviral E1-complementing sequences;

3) transfecting, under conditions whereby said recombinant adenovirus vector library is produced;
4) transfecting a first recombinant nucleic acid comprising adenoviral sequence coding, in operable configuration, for one functional Inverted Terminal Repeat, and sequence coding for a promoter and a unique nucleic acid operatively linked to said promoter;
5) transfecting a second recombinant nucleic acid comprising adenoviral sequence coding, in operable configuration, for one functional Inverted Terminal Repeat and sufficient for replication, wherein said second recombinant nucleic acid does not comprise the

comprise the adenoviral E1 region; and,

6) requiring the recombinant nucleic acids comprises a functional encapsidation signal.

Claim 1 does not disclose any of these elements. Further, claims 3-7, 10, 11, 16, and 21-25 do not disclose any of these elements.

When weighing all of the factors, claim 7 of the '776 patent is not obvious in light of the claim 1 of the present application and its prior art, or any of the claims depending therefrom.

Again, the *a contrario* argument, claim 7 of the '776 patent has as earliest priority date June 12, 1998, or, three years after that of the presently claimed invention. Therefore, since the presently claimed subject-matter was publicly disclosed by the time the earliest priority document of the '776 patent was filed (June 12, 1998), the '776 claims that were granted fulfilled the criteria for patentability, *i.e.* were non-obvious over the present claims and underlying disclosure. Therefore, the allegation that the claims are not patentably distinct is unjustified and Applicants respectfully request reconsideration and withdrawal of the rejection.

Likewise, claim 32 of the '776 patent is dependent from claim 24 therein, and therefore should read substantially as follows:

> A method of producing a recombinant adenovirus vector library consisting essentially of distinct recombinant adenoviral vectors each distinct vector containing a unique nucleic acid, said method comprising:
> growing a plurality of cell cultures containing at least one cell, said one cell expressing adenoviral sequence consisting essentially of E1-region sequences and expressing one or more functional gene products encoded by at least one adenoviral region selected from an E2A region and an E4 region; and
> transfecting, under conditions whereby said recombinant adenovirus vector library is produced, said at least one cell in each of said plurality of cell cultures with
> i) an adapter plasmid comprising adenoviral sequence coding, in operable configuration, for a functional Inverted Terminal Repeat, a functional encapsidation signal, and sequences sufficient to allow for homologous recombination with a first recombinant nucleic acid, and not coding for E1 region sequences which overlap with E1 region sequences in said at least one cell, for E1 region sequences which overlap with E1 region sequences in a first recombinant nucleic acid, for E2B region sequences other than essential E2B sequences, for E2A region sequences, for E3 region sequences and for E4 region sequences, and further comprises a unique nucleic acid sequence and promoter operatively linked to said unique nucleic acid sequence; and
> ii) a first recombinant nucleic acid comprising adenoviral sequence coding, in

operable configuration, for a functional adenoviral Inverted Terminal Repeat and for sequences sufficient for replication in said at least one cell, but not comprising adenoviral E1 region sequences which overlap with E1 sequences in said at least one cell, and not comprising E2A region sequences or E4 region sequences expressed in said plurality of cells which would otherwise lead to production of replication competent adenovirus wherein said first recombinant nucleic acid has sufficient overlap with said adapter plasmid to provide for homologous recombination resulting in production of recombinant adenovirus in said at least one cell,
wherein said at least one cell is a PER.C6 cell culture.

The underlined portion herein indicates the subject-matter that distinguishes this claim from present claim 1. As can be seen, the underlined part renders these claims patentably distinct from each other. Claim 32 of the '776 patent relates to a process for creating a recombinant adenovirus vector library that can be used in functional genomics. In contrast, present claim 1 relates to an isolated adenovirus packaging cell comprising in its genome a first nucleic acid molecule encoding adenovirus E1A and E1B gene products but lacking a nucleic acid sequence encoding adenovirus pIX, and therefore it is clear that the scope of claim 32 of the '776 patent does not render obvious or overlap with the scope of present claim 1.

Further, the cell culture of the claim 32 specifically claims the element of functional gene products encoded by at least one adenoviral region selected from an E2A region and an E4 region. Claim 1 has no such element and should not be found obvious.

Further, the fact that the present invention is patentably distinct and pertains to a fully unrelated invention from that claimed in claim 32 of the '776 patent is further underscored by the fact that the '776 patent has as an earliest priority date of June 12, 1998, and therefore the invention covered therein was filed three years after the presently claimed invention. Therefore, the *a contrario* argument again applies. The presently claimed subject-matter of claim 1 was publicly disclosed by the time the earliest priority document for the '776 patent was filed (June 12, 1998), so the granted '776 claims must have fulfilled the criteria for patentability, *i.e.*, must have been viewed as being non-obvious over the present disclosure and claims.

Moreover, claim 35 of the '776 patent is dependent from claim 34 therein, which in turn is the product of the process in claim 24. Hence, the arguments provided previously for claim 32 apply similarly with the necessary changes having been made, for claim 35 of the '776 patent.

Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1, 3-7, 9-11, 16, and 22 in light of this response and the amendments.

b) Crucell, f.k.a. Introgene, patents

Claims 1, 3-7, 9-11, 16 and 22 stand rejected under the judicially created doctrine of ODP as being assertedly unpatentable over claim 3 of the '519 patent. Claims 1, 3-7, 9, 16, 21 and 24 stand rejected under the judicially created doctrine of ODP as being assertedly unpatentable over claim 11 of the '768 patent. Claims 1, 3-7, 9-11, 16 and 21-24 stand rejected under the judicially created doctrine of ODP as being assertedly unpatentable over claims 1-5 of the '188 patent. Claims 1, 3-7, 9, 16 and 21 stand rejected under the judicially created doctrine of ODP as being assertedly unpatentable over claims 1-13 of the '794 patent; claims 2, 4, and 6 of the '549 patent; and claims 15, 19 and 26 of the '544 patent. Terminal disclaimers are filed herewith for the '519 patent, the '768 patent, the '188 patent, the '794 patent, the '549 patent, and the '544 patent. Reconsideration and withdrawal of these rejections is respectfully requested in view of the terminal disclaimers.

iii) Pending Applications

In reference to the applications, the provisional ODP rejections, Applicants respond as follows:

Claims 1, 3-7, 9, 16 and 21 stand provisionally rejected under the judicially created doctrine of ODP as being allegedly unpatentable over claims 18-22 of Application 10/002,750 (hereinafter referred to as the '750 application). The '750 application has issued on December 13, 2005 as US Patent 6,974,695. With respect to US Patent 6,974,695, applicants herewith file a terminal disclaimer to overcome the rejection. Applicants respectfully request reconsideration of the rejection in view of this terminal disclaimer.

Claims 1, 3-7, 9, 16 and 21 stand provisionally rejected under the judicially created doctrine of ODP as being allegedly unpatentable over claims 67 and 95 of co-pending Application No, 10/036,949 (hereinafter referred to as the '949 application); claims 70-100 of co-pending Application No. 10/136,139 (hereinafter referred to as the '139 application); claim 33 of co-pending Application 10/432,105 (hereinafter referred to as the '105 application); claims 98 and

and 107 of co-pending Application No. 10/494,140 (not abbreviated hereinafter); claims 51, 67 and 82 of co-pending Application 10/497,832 (hereinafter referred to as the '832 application); claims 27 and 54 of co-pending Application No. 10/512,589 (hereinafter referred to as the '589 application); claim 5 of co-pending Application 10/644,256 (hereinafter referred to as the '256 application); claim 8 of co-pending Application 10/850,140 (not abbreviated hereinafter); claims 8, 35, and 58 of co-pending Application No. 11/039,767 (hereinafter referred to as the '767 application); and claim 11 of co-pending Application No. 11/083,590 (hereinafter referred to as the '590 application). Claims 1, 3-7, 9-11, 21 and 24 stand provisionally rejected under the judicially created doctrine of ODP as being allegedly unpatentable over claims 1-6, 30-33, 35-38, and 40-50 of co-pending Application 10/038,271 (hereinafter referred to as the '271 application), and claims 1-31 of co-pending Application No. 11/134,674 (hereinafter referred to as the '674 application). Applicants note that the claims are only provisionally rejected, as no patent has issued.

With respect to Claims 67 and 95 of the '949 application (assigned to Galapagos), applicants submit that the allegedly conflicting claims have not yet been granted in a patent and therefore it is appropriate to postpone the rejection until a patent would be issued from the '949 application. In this regard it is to be noted that the '949 application has as earliest priority date June 12, 1998, and therefore any invention covered therein was made several years after the presently claimed invention, as is a theme with all of the rejections. The arguments provided supra for the '595 and the '776 patents apply mutatis mutandis for this application, which is related to those patents.

With respect to the '139 application, Applicants respectfully request reconsideration in light of the Notice of Abandonment mailed November 2, 2005 in the '139 application.

With respect to the '105 application, application 10/494,140, the '832 application, the '589 application, the '256 application, application 10/850,140, the '767 application, the '590 application, the '271 application and the '674 application, applicants herewith file a terminal disclaimer to overcome the rejection. Applicants respectfully request reconsideration and withdrawal of the provisional rejections in light of this response.

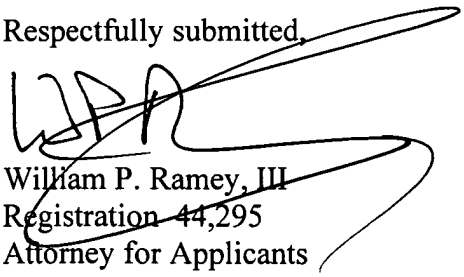
The Examiner further contends that the '674 application, the '590 application, and application 10/850,140 appear assigned to their inventors. However, the inventors have assigned

the invention to Crucell Holland B.V. The publication of the '674 application (publication no. US 20050221492 A1, published October 6, 2005) on its front page mentions Crucell as the assignee. USSN 10/850,140 is a continuation application of serial number 09/918,029, which is a divisional application of serial number 09/506,548 (hereinafter the '548 application). The '548 application and any divisional or continuation applications thereof were assigned to Introgene, as recorded on October 2, 2000, reel/frame 011151/0287. The name change of Introgene to Crucell was recorded at reel/frame 013828/0651 on March 11, 2003. Accordingly, USSN 10/850,140, being a successor to the '548 application, is assigned to Crucell. Likewise, the '590 application is a continuation application of serial number 10/010,645 (hereinafter the '645 application). the '645 application and any continuation applications thereof was assigned to Crucell, as recorded on June 11, 2002 at reel/frame 012976/0445. Therefore, the '590 application, being a successor to the '645 application, is assigned to Crucell. Therefore the '674 application, the '590 application, and application 10/850,140 are commonly owned with the current application, and terminal disclaimers can be filed.

CONCLUSION

Entry of the foregoing amendments and reconsideration of the rejections is respectfully requested. The Examiner is invited to contact Applicants' attorney, Allen Turner, at (801) 532-1922 for any assistance.

Respectfully submitted,



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